

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/699,212 Confirmation No.: 2780
Applicant : David R. Hennings
Filing Date : October 30, 2003
Title : Endovenous Closure of Varicose Veins with Mid-Infrared Laser
Group Art Unit : 3735
Examiner : David M. Shay
Docket No. : 15487.4002
Customer No. : 34313

MAIL STOP REPLY BRIEF
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Sir:

The Prior Art Teaches Away From the Invention

We will first discuss and refute the arguments made in the Examiner's Answer at pages 23-25 which, in turn, are directed to pages 23-31 of Appellant's Opening Brief. The issue discussed in these portions of the Opening Brief and the Examiner's Answer is the fact that the prior art taught against the invention claimed in the present application. In this regard, it is important to keep in mind that the invention claimed in the present application comprises a method and system for treating varicose veins using laser energy having a wave length between about 1.2 and 1.8 μm . Appellants do not claim to be the first to treat varicose veins with lasers, that was done by Navarro as disclosed in his patent number 6,398,777. However, Navarro teaches the use of laser energy having wave lengths of 500-1100 nm, preferably 532 nm-1064 nm to treat varicose veins and the contemporary scientific literature explains:

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(a) That, prior to the present invention, Navarro and all other prior art workers targeted the hemoglobin in blood as the chromophore which would be treated with laser energy.

(b) The wavelengths for which hemoglobin was a chromophore were in the range of 810-980 nm.

(c) Wavelengths of 1064 nm or greater were considered undesirable because of adverse effects on patients.

Plainly, evidence that the prior art has taught away from a claimed invention is strong evidence of unobviousness, Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314, 1326-27 (Fed. Cir. 2009). However, not only has the Examiner failed to rebut this evidence of unobviousness, he has persistently refused to reject the claims over the closest prior art, the Navarro '777 patent.

The Examiner's refusal to recognize the existence of the evidence that the prior art taught away from the present invention is reflected in his assertion at page 18 that:

There is no assertion whatsoever in any affidavit of record that the articles or product literature are in any way representative of the prior art with respect to varicose vein treatment.

This statement is in direct conflict with paragraph 6 of the Henning's Declaration dated December 22, 2008, Appendix 4, which states:

6. The articles from the scientific literature attached as Exhibits A, B and C to the aforesaid Geriak Declaration are fully representative of the prior art with respect to varicose vein treatment and are from highly respected scientific journals.

Paragraph 10 of the Henning's Declaration dated December 22, 2008, goes on to say:

10. Based on my own firsthand knowledge, I can state unequivocally that the examiner was incorrect in refusing, at page 11 of

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the examiner's answer, to accept the assertions of our counsel, Mr. Geriak, that Exhibits A, B and C to his declaration were representative of the prior art. Furthermore, I believe that the Fan-Rox-Anderson article attached hereto is fully consistent with the face that Exhibits A, B and C attached to the aforesaid Geriak Declaration are representative of the prior art.

With regard to the Fan-Rox-Anderson article which is attached to the Henning's Declaration, and which appeared in the highly-regarded scientific journal *Phlebology* in 2008 (paragraph 7 of Henning's Declaration), Henning declares in paragraph 9:

9. The Fan-Rox-Anderson article also cited to Navarro Patent No. 6,398, 777 (which the examiner states to be of "little moment" at page 9 of the examiner's answer), but does not mention or cite to any of the irrelevant prior art relied upon by the Examiner. Furthermore, at page 209 of the Fan-Rox-Anderson article, the authors contrast the performance of the laser having a wavelength of 1320 nm with lasers having wavelengths of 810-1064 nm and conclude that there appears to be substantial patent benefit which results from the use of the wavelength of 1320 nm as recited in the claims of this application as compared with the 810-1064 nm wavelengths used by the prior art.

Similarly, paragraph 8 of the Goldman Declaration dated December 23, 2008, Appendix 5, states as follows:

Our use of laser wavelengths in the range 12-188 nm as claimed in the present application was contrary to the view held by prior art workers that such wavelengths would be undesirable, a view expressed in the Min and Proebstle articles which are attached to the Geriak Declaration as Exhibits A, B and C and which are representative of the belief held by the prior art prior to the invention claimed in this application.

Thus, there is compelling evidence, which is totally un rebutted, that not only did the prior art teach away from the present invention, but that the present invention has provided substantial patent benefit.

The Examiner's answer, rather than attempting to rebut any of the foregoing evidence, attempts, at pages 23 and 24, to rely on the Goldman '084 patent, which, other than its passing

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reference to lasers, is directed only to a description of the use of RF energy, which is totally different from and irrelevant to laser energy because it does not function by exciting chromophores to cause heating, but rather operates on the basis of resistance heating, as basis for his argument that "the use of hemoglobin as the chromophore is immaterial in view of the specific call by Goldman et al. ('084) to use constituents of the vessel wall as chromophores." This assertion is profoundly erroneous. Goldman makes no mention of chromophores and the Examiner's reference to the fifth and sixth sentences of the Abstract of Goldman is inexplicable.

Then, in the paragraph bridging pages 24 and 25, the Examiner states, with regard to the Henning Declaration, Appendix 4, dated December 22, 2008:

Declarant never expressly states that it is Declarant's belief that these articles are representative.

This statement is implacably at odds with paragraph 6 of the Henning's Declaration which states:

"The articles from the scientific literature attached as Exhibits A, B and C to the aforesaid Geriak Declaration are fully representative of the prior art with respect to vascular vein treatment and are from highly respected scientific journals."

Further, at page 25, the Examiner's attempt to cope with the statement in paragraph 8 of the Goldman Declaration, Appendix 5, that the use of the wavelength claimed in the present application was "contrary to the view held by prior art workers that such wavelengths would be undesirable", states:

"However, there is no negative statement whatsoever in any of the submitted articles with respect to the undesirability of any wavelength range."

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This statement by the Examiner flies in the face of the unanimous teachings of the prior art that wavelengths in the 810-940 nm range were considered desirable and that, e.g., at page 995 of the Min article attached as Exhibit A to the Geriak Declaration, that wavelengths such as wavelengths 1064 nm were undesirable. Similarly, the Navarro '777 patent which the Examiner has not used a basis for rejection, but upon which he relies in his argument at page 23 of the Examiner's Answer, taught an upper limit of 1100 nm. On top of this, the Fan/Rox-Anderson article, at page 209, clearly recognizes unequivocally that the present invention was a departure from the prior art.

Goldman '084 Is Not An Effective Reference Because Of Lack Of Enablement.

The Work Of Navarro Cannot Remedy The Deficiencies Of Goldman Because The Claims Have Never Been Rejected On The Basis Of Navarro.

On pages 9 and 19 of the Examiner's Answer, the Examiner relies upon the Bone publication which is not of record, but is the reference cited in footnote 11 of the Min article attached as Exhibit A to Appendix 2, the Geriak Declaration. As shown in footnote 12, Bone was a co-worker with Navarro and Min with regard to the use of an 810 nm laser to treat varicose veins, i.e., the work reflected in Navarro Patent No. 6,398,777. The Examiner's attempt to rely on the work of Bone to provide the enablement which is lacking in Goldman is improper.

Similarly, at page 19, the Examiner attempts to rely on Navarro '777 to support his rejection based on Goldman. Plainly, all of the discussion about the lack of enablement in Goldman could have been avoided if the Examiner had rejected the claims in this application on the basis of Navarro. His failure to do so has made it necessary for Applicant and this Board to deal with issues that would not have to be addressed if a rejection based on Navarro had been made.

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The Goldman Declaration Rebutts Any Presumption Of Operability That Might Exist.

At page 11 of the Examiner's Answer, the Examiner asserts, without any citation of authority, that a presumption of operability arises from the inventor's oath filed with the application which became the '084 patent. Applicant is unaware of any such presumption, but, in any event, if such presumption did exist, it is squarely rebutted by paragraph 5 of the Goldman Declaration, Appendix 5 which states:

"Prior to filing the application which became Patent No. 6,258,084, we had no experience or knowledge which would permit us to enable the use of lasers to treat varicose veins. For example, we did not know which laser wavelengths might be useful nor did we know what power levels might be safe and effective."

At page 11 of the Examiner's Answer, the Examiner attempts to rely on the breadth of claim 1 of the Goldman patent, which does not specify any type of energy, as support for his position that Goldman '084 enables lasers. This argument makes no sense. The fact is that claim 1 is not enabled and the lack of enablement in claim 1 cannot be the basis for an argument that the specification enables claim 1. The unalterable fact is that the Goldman Declaration states that the inventors of Goldman '084 did not know how to enable the use of lasers in the treatment of varicose veins.

Navarro Cannot Be Relied Upon To Support An Obviousness Argument Based On Goldman.

At page 19 of the Examiner's Answer, the Examiner attempts to buttress his argument that the claims in this application are obvious over Goldman '084 by reliance on the fact that Navarro '777 was filed a few months after Goldman '084. This attempted, but improper, reliance on Navarro

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which the Examiner has refused to use as the basis for a rejection, is, we submit, a self-recognition by the Examiner that his obviousness rejection based on Goldman is too weak to be sustained.

NOTICE OF CO-PENDING APPLICATION

Applicant herewith gives notice that claims in their application serial no. 11/562,944, filed November 22, 2006 is related to the present application and a Terminal Disclaimer has been filed in that application which disclaims any term which would extend beyond the term of any patent issued on the present application. Serial No. 11/562,944 is being prosecuted by an attorney who is not affiliated with the law firm responsible for the present application

CONCLUSION

For the reasons stated above and for the reasons stated in Applicant's Opening Brief, it is respectfully submitted that all of the rejections made by the Examiner are in error and should be reversed.

Applicant hereby requests that an Oral Hearing be scheduled in this application. The Commissioner is hereby authorized to charge any fees associated to Deposit Account No. 15-0665.

Fees

The Commissioner is authorized to charge Orrick's Deposit Account No. 15-0665 for any fees required and credit any overpayments to said Deposit Account No. 15-0665.

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Respectfully submitted,

Orrick, Herrington & Sutcliffe, LLP

Dated: April 19, 2010

By: 
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